

REMARKS

Claim 3 has been cancelled, without prejudice.

Claim 1 has been amended to recite "[a] process for producing canthaxanthin and echinenone, which comprises:

(a) cultivating in an aqueous nutrient medium a recombinant *Xanthophyllomyces dendrorhous* (*Phaffia rhodozyma*) microorganism that comprises a polynucleotide sequence that encodes a β -carotene ketolase, wherein β -carotene accumulates in the medium under aerobic conditions, and

(b) isolating carotenoids from the recombinant microorganism or from the medium, wherein the polynucleotide sequence is originated from a microorganism which is selected from the group consisting of *Agrobacterium aurantiacum*, *Alcaligenes* PC-1, *Paracoccus marcusii* MH1, a gram-negative bacteria E-396 (FERM BP-4283), and *Haematococcus pluvialis*." Support for this amendment is found in the specification at, for example, page 2, lines 22-30; page 6, lines 5-8; in Example 2; and in original claims 2 and 3. See *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l) (8th ed. Rev. 5, August 2006, pp. 600-92 and 600-84).

Claim 2 has been amended to remove the phrase "or a mutant thereof."

Claim 4 has been amended to remove the phrase "or the DNA sequence of the β -carotene ketolase gene is substantially homologous thereto."

Claim 5 has been amended to recite "using a control sequence." This amendment is for clarification purposes only and does not change the scope of the claim in any way.

Claim 6 has been amended to recite "a pH in the range of from 4 to 8."
Support for this amendment is found in the specification at, for example, page 5, lines 18-19. (*Id.*).

Claim 7 has been amended to depend from claim 6.

Claim 8 has been added to recite isolating canthaxanthin and echinenone.
Support for this amendment is found in original claim 1.

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

INTERVIEW SUMMARY

The Examiner is thanked for the courtesies extended during a telephonic Interview conducted with the undersigned on April 2, 2007. During the interview, the foregoing amendments and the pending rejections under 35 USC § 112, first paragraph, and 35 USC § 103 were discussed. The Examiner agreed to review the rejections in view of the amendments presented above and the remarks presented below. The Examiner also agreed that the amendments presented above would likely place the application in condition for allowance. Therefore, in view of the amendments and remarks below, withdrawal of the rejections and allowance of the claims are respectfully requested.

Indefiniteness Rejections:

Claims 1-5 were rejected under 35 USC § 112, second paragraph.
(Paper No. 20060627 at 2-4).

In making the rejection of claim 1, the Examiner asserted that "claim 1 recites the β -carotene ketolase gene and belonging to belonging to the genus

Xanthophyllomyces (Phaffia)' which is unclear as written as it sounds like the β -carotene ketolase gene must be from *Phaffia* and not that the microorganism is a *Phaffia* strain." (*Id.* at 2-3).

With a view towards furthering prosecution, claim 1 has been amended to recite "cultivating in an aqueous nutrient medium a recombinant *Xanthophyllomyces dendrorhous (Phaffia rhodozyma)* microorganism that comprises a polynucleotide sequence that encodes a β -carotene ketolase" In view of the foregoing, the rejection of claim 1 is rendered moot. Accordingly, withdrawal of the rejection is respectfully requested.

Claim 2 was also rejected under 35 USC § 112, second paragraph. (*Id.* at 3). In making the rejection, the Examiner asserted that the phrase "mutant thereof" is "unclear." (*Id.*).

With a view towards furthering prosecution, claim 2 has been amended to remove the phrase "mutant thereof." In view of the foregoing, the rejection of claim 2 is rendered moot. Accordingly, withdrawal of the rejection is respectfully requested.

Claim 3 was also rejected under 35 USC § 112, second paragraph. (*Id.*). In making the rejection, the Examiner asserted that "claim 3 is confusing as it includes E-396 (FERM BP-4283) as a source of β -carotene ketolase gene but claim 1 from which it depends recites that the β -carotene ketolase gene must be from *Agrobacterium*, *Alcaligenes*, *Paracoccus* or *Haematococcus*." (*Id.*).

With a view towards furthering prosecution, claim 3 has been cancelled, without prejudice, and claim 1 has been amended to incorporate the subject matter of

(a) cultivating in an aqueous nutrient medium a recombinant ***Xanthophyllomyces dendrorhous (Phaffia rhodozyma)*** microorganism that comprises a polynucleotide sequence that encodes a β -carotene ketolase, wherein β -carotene accumulates in the medium under aerobic conditions, and

(b) isolating carotenoids from the recombinant microorganism or from the medium, wherein the polynucleotide sequence is originated from a microorganism which is **selected from the group consisting of *Agrobacterium aurantiacum*, *Alcaligenes* PC-1, *Paracoccus marcusii* MH1, a gram-negative bacteria E-396 (FERM BP-4283), and *Haematococcus pluvialis*.**"

As amended, claim 1 recites a ***specific recombinant microorganism***, namely, *Phaffia rhodozyma*. In addition, amended claim 1 recites ***specific microorganisms where the β -carotene ketolase gene is originated from***, namely *Agrobacterium aurantiacum*, *Alcaligenes* PC-1, *Paracoccus marcusii* MH1, a gram-negative bacteria E-396 (FERM BP-4283), and *Haematococcus pluvialis*. Support for these amendments is found virtually *in haec verba* in the specification. (See, e.g., Specification at page 2, lines 22-30; page 6, lines 5-8; in Example 2; and in original claims 2 and 3). Claim 1 is also specifically tied to a recited function, namely "expressing a β -carotene ketolase gene." Accordingly, the recombinant microorganism recited in claim 1 is specifically tied to a function. Thus, there is a built-in tie between the recited recombinant microorganism and function. Also, the claim recites specific microorganisms where the β -carotene ketolase gene is originated from. Moreover, the specification exemplifies ways to obtain the currently claimed microorganisms. (See, e.g., page 2, lines 22-30, page 4, line 19 - page 5, line 23, and Examples 1-2). Nothing

cancelled claim 3. In view of the foregoing, the rejection of claim 3 is rendered moot. Accordingly, withdrawal of the rejection is respectfully requested.

Claim 4 was also rejected under 35 USC § 112, second paragraph. (*Id.*). In making the rejection, the Examiner asserted that the phrase "substantially homologous thereto" is "unclear." (*Id.*).

With a view towards furthering prosecution, claim 4 has been amended to remove the phrase "substantially homologous thereto." In view of the foregoing, the rejection of claim 4 is rendered moot. Accordingly, withdrawal of the rejection is respectfully requested.

Claim 5 was also rejected under 35 USC § 112, second paragraph. (*Id.* at 4-5). In making the rejection, the Examiner asserted that the term "control sequence" lacks antecedent support and that the term is "indefinite and vague." (*Id.* at 5). The Examiner then asked "Does 'control sequence' mean control regulatory sequence or something else?" (*Id.*).

With a view towards furthering prosecution, claim 5 has been amended to recite proper antecedent support. Furthermore, we remind the Examiner that the legal standard for definiteness is whether a claim reasonably apprises those of skill in the art of its scope. *In re Warmerdam*, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994). Here, amended claim 5 meets that standard by explicitly defining the term "control sequence" in the specification at page 3, lines 26-30:

The term "control sequence" is intended to include, at a minimum, components which are necessary for expression of the gene of interest, and may also include additional advantageous components. Generally the control sequences include promoters, terminators and, in some

instances, enhancers, transactivators, or transcription factors.

Nothing more need be provided. In view of the foregoing, it is submitted that the rejection of claim 5 is rendered moot. Accordingly, withdrawal of the rejection is respectfully requested.

§112, First Paragraph Rejections:

1. Written Description

Claims 1-7 were rejected under 35 U.S.C. §112, first paragraph. (Paper No. 20060627 at 4). In making the rejection, the Examiner asserted that claims 1-7 "contain[] subject matter, which was not described in specification" (*Id.*). The Examiner further asserted that "[t]he specification teaches the structure of only a single representative species of [] β -carotene ketolase genes." (*Id.* at 5). The Examiner also asserted that "the specification fails to describe any other representative species by additional identifying characteristics or properties other than the functionality of the gene encoding polypeptide of β -carotene ketolase." (*Id.*). The Examiner then concluded that "[g]iven this lack of description of representative species encompassed by the genus of genes used in the claim[s], the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention." (*Id.* at 5-6).

With a view towards furthering prosecution, however, claim 1 has been amended to recite "[a] process for producing canthaxanthin and echinenone, which comprises:

more need be provided. Thus, in view of these amendments, it is respectfully submitted that the claims fully satisfy the written description requirement.

In view of the foregoing, it is respectfully submitted that the rejection has been rendered moot and should be withdrawn.

2. Enablement

Claims 1-7 were rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. (Paper No. 20060627 at 6). In making the rejection, the Examiner acknowledged that the specification is "enabling for a process for producing canthaxanthin and echinenone by using a recombinant microorganism of *Phaffia rhodozyma* expressing β -carotene ketolase gene from *Alcaligenes* strain PC-I (GenBank Accession No. D58422)." (*Id.*).

The Examiner, however, asserted that "the specification does not reasonably provide enablement for a process for producing canthaxanthin and echinenone by using any β -carotene ketolase gene from any source." (*Id.*).

Initially, we note it is the Examiner's burden to demonstrate that a specification is not sufficiently enabling. *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). To carry his/her burden, the Examiner must identify and clearly articulate the factual bases and supporting evidence that allegedly establish that undue experimentation would be required to carry out the claimed invention. *Id.* at 370. It is well established that claims must be separately analyzed. *Ex parte Jochim*, 11 USPQ2d 561 (BPAI 1988).

With a view towards furthering prosecution, claim 1 has been amended as noted above. As amended, claim 1 recites a ***specific recombinant microorganism***,

namely, *Phaffia rhodozyma*, which the Examiner conceded is enabled. (Paper No. 20060627 at 6). In addition, amended claim 1 recites ***specific microorganisms where the β -carotene ketolase gene is originated from***, namely *Agrobacterium aurantiacum*, *Alcaligenes* PC-1, *Paracoccus marcusii* MH1, a gram-negative bacteria E-396 (FERM BP-4283), and *Haematococcus pluvialis*. Moreover, claim 1 is specifically tied to a recited function, namely “expressing a β -carotene ketolase gene.” With these amendments, it is respectfully submitted that the Examiner’s concerns regarding the scope of claim 1, *i.e.*, “any β -carotene ketolase gene by culturing and expressing in any strains of Xanthophyllomyces,” is rendered moot. (Paper No. 20060627 at 6) (emphasis original).

Moreover, as is well accepted, even a “considerable amount” of experimentation is permissible if it is merely routine or if the specification provides a reasonable amount of guidance. MPEP § 2164.05 and *In re Wands*, 8 USPQ at 1404. In addition, “a patent need not teach, and preferably omits, what is well known in the art.” MPEP § 2164.01 (8th ed. Rev. 5, August 2006, p. 2100-187) *citing In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

In this regard, we note that the specification provides ample disclosure sufficient to inform a skilled artisan that the Applicants enabled the currently claimed recombinant microorganisms. For example, the specification discloses 2 examples that

provide sufficient instruction to one skilled in the art on how to make and use the currently claimed **specific** recombinant microorganisms.

The specification also discloses how to obtain and use the **specific microorganisms where the β -carotene ketolase gene is originated from**, namely *Agrobacterium aurantiacum*, *Alcaligenes* PC-1, *Paracoccus marcusii* MH1, a gram-negative bacteria E-396 (FERM BP-4283), and *Haematococcus pluvialis*, recited in amended claim 1. (See, e.g., Specification page 2, lines 22-30, page 4, line 19 - page 5, line 23, and Examples 1-2). Thus, identifying the recombinant microorganisms capable of producing canthaxanthin and echinenone according to the process of amended claim 1 is a matter of applying the disclosure in the specification of how to make such recombinant microorganisms and testing the ability to produce canthaxanthin and echinenone productions of the recombinant microorganisms. (See Specification at page 9, lines 25-33). It is respectfully submitted that such activity is not undue experimentation.

For the reasons set forth above, it is respectfully submitted that the rejection has been rendered moot and should be withdrawn.

Rejection Under 35 USC § 103:

Claims 1-7 were rejected under 35 USC § 103 as being unpatentable over Misawa, N. *et al.*, GenBank Accession No. 058422, *Alcaligenes* sp. crtW and crtZ genes for beta-carotene hydroxylase and beta-carotene ketolase, complete cds (1995) ("Misawa I") and Misawa, N. *et al.*, "Canthaxanthin Biosynthesis By The Conversion Of Methylene To Keto Groups In A Hydrocarbon β -Carotene By A Single Gene," Biochemical And Biophysical Research Communications, vol. 209, no. 3, pp. 867-876

(1995) ("Misawa II") in view of Hoshino *et al.*, U.S. Patent No. 6,365,386 ("Hoshino").
(Paper No. 20060627 at 9-10).

The rejection respectfully is traversed.

Misawa I discloses the isolation of beta-carotene ketolase from strain
Alcaligenes PC-1 (GenBank accession No. D58422).

Misawa II discloses that "[a] novel gene involved in ketocompound biosynthesis, designated *crtW*, was isolated from the marine bacteria *Agrobacterium aurantiacum* and *Alcaligenes* PC-1 that produce ketocarotenoids such as astaxanthin." (Abstract). Misawa II further discloses that "[w]hen this gene was introduced into *Escherichia coli* that accumulated β -carotene due to the *Erwinia* carotenogenic genes, the *E. coli* transformants synthesized canthaxanthin" (*Id.*). "It has been therefore surprisingly substantiated that one gene *crtW* encodes an enzyme that catalyzes the conversion of methylene groups of a hydrocarbon β -carotene to keto groups for synthesizing canthaxanthin." (Page 874).

Hoshino discloses that "*Phaffia rhodozyma* (*P. rhodozyma*) is a carotenogenic yeast strain which produces astaxanthin." (Col. 1, lines 1-2). Hoshino further discloses "a gene and an enzyme which is involved in the last step of astaxanthin biosynthesis (i.e., from beta-carotene to astaxanthin)." (Col. 2, lines 29-31).

In making the rejection, the Examiner asserted that Misawa I discloses "isolation of a beta-carotene ketolase (*crtW*) gene from *Alcaligenes* PC-1 strains, which is 100% identical to the said gene disclosed by the instant application." (Paper No. 20060627 at 9). The Examiner acknowledged, however, that Misawa I "do[es] not

teach the use of the gene for a process for producing canthaxanthin and echinenone.”
(*Id.*).

The Examiner asserted that Misawa II discloses “a method of producing canthaxanthin and echinenone from beta-carotene by using a recombinant *E. coli* comprising beta-carotene ketolase gene (*crtW*) from *Alcaligenes* PC-I.” (*Id.*). The Examiner also asserted that Misawa II discloses “cloning said gene in [an] expression vector, which is under the control of a promoter, transform[ing] an *E. coli* and culturing the said recombinant microorganism at 28°C and produced canthaxanthin and echinenone.” (*Id.*). The Examiner acknowledged, however, that Misawa II “do[es] not teach the use of transformed *Phaffia rhodozyma* by the said gene for producing canthaxanthin and echinenone.” (*Id.*).

To fill the acknowledged gaps in Misawa I and Misawa II, the Examiner relied on Hoshino for “disclos[ing] a process for producing astaxanthin from beta-carotene in *Phaffia rhodozyma* ATCC96815 comprising all the genes required to produce astaxanthin” (*Id.*). The Examiner further asserted that Hoshino “disclose[s] ... a mutant strain of *Phaffia rhodozyma*, which is blocked for the astaxanthin production i.e. this mutant strain will produce mainly canthaxanthin, and echinenone.” (*Id.* at 10).

The Examiner then **admitted** that Hoshino “do[es] not disclose the isolation of the beta-carotene ketolase gene from *Alcaligenes* PC-I [] and expression of beta-carotene ketolase in said recombinant microorganism using control sequences or culturing the recombinant microorganism for 48-350 hours.” (*Id.*).

The Examiner then contended that “[i]t would have been obvious to one [of] ordinary skill in the art ... to combine the teaching of Misawa [I], Misawa [II] and Hoshino et al. to produce canthaxanthin and echinenone from beta-carotene by using the beta-carotene ketolase gene (crtW) of Misawa et al. (GenBank) to transform the *Phaffia rhodozyma* of Hoshino et al. to produce canthaxanthin and echinenone by using the methods of Hoshino et al.” (*Id.*).

With a view towards furthering prosecution, claim 1 has been amended to recite “[a] process for producing canthaxanthin and echinenone, which comprises:

(a) cultivating in an aqueous nutrient medium a recombinant ***Xanthophyllomyces dendrorhous (Phaffia rhodozyma)*** microorganism that comprises a polynucleotide sequence that encodes a β -carotene ketolase, wherein β -carotene accumulates in the medium under aerobic conditions, and

(b) isolating carotenoids from the recombinant microorganism or from the medium, wherein the polynucleotide sequence is originated from a microorganism **which is selected from the group consisting of *Agrobacterium aurantiacum*, *Alcaligenes* PC-1, *Paracoccus marcusii* MH1, a gram-negative bacteria E-396 (FERM BP-4283), and *Haematococcus pluvialis*.**”

It is well settled that the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO should include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the documents relied on by the Examiner as evidence of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 2007 U.S. LEXIS 4745, *37-39 (April 30, 2007) (the obviousness “**analysis should be made explicit**” and the teaching-suggestion-motivation test is “**a helpful insight**” for determining obviousness) (emphasis added); *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). Moreover, the factual inquiry whether to combine documents must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion to combine “**must be based on objective evidence of record**.” *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002) (emphasis added).

The rejection is devoid of *any* evidence - or even argument - in support of the proposed combination. All that is there is a conclusory statement that “[i]t would have been obvious to one [of] ordinary skill in the art” then some circular hindsight reasoning (“obvious ... to combine the teaching of Misawa [I], Misawa [II] and Hoshino et al. to produce canthaxanthin and echinenone from beta-carotene by using the beta-carotene ketolase gene (crtW) of Misawa et al. (GenBank) to transform the *Phaffia rhodozyma* of Hoshino et al. to produce canthaxanthin and echinenone by using the methods of Hoshino et al.”). (Paper No. 20060627 at 10). What the rejection should have done, but did not, was to explain on the record **why** one skilled in this art would modify the disclosure of Misawa I and II using Hoshino to arrive at the claimed method. As is well settled, an Examiner cannot establish obviousness by locating references

which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). Thus, the rejection is legally deficient and should be withdrawn for this reason alone.

Notwithstanding the legally insufficient nature of the rejection, we note that the rejection is also factually insufficient to support a rejection under § 103(a). In doing so we observe that obviousness cannot be based upon speculation, nor can obviousness be based upon possibilities or probabilities. Obviousness **must** be based upon facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). When a conclusion of obviousness is not based upon facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993). Further, "to establish *prima facie* obviousness of a claimed invention, **all claim limitations must be taught or suggested by the prior art.**" MPEP § 2143.03 (citing *In re Royka*, 180 USPQ 580 (CCPA 1974)) (emphasis added).

Assuming *arguendo* that Misawa I and II are properly combinable with Hoshino, which they are not, such a combination does not produce amended claim 1, from which claims 2 and 4-7 either directly or indirectly depend. As acknowledged by the Examiner, Misawa I "do[es] not teach the use of [β -carotene ketolase gene] for a process for producing canthaxanthin and echinenone," and Misawa II "do[es] not teach the use of transformed *Phaffia rhodozyma* by the said gene for producing canthaxanthin and echinenone." (Paper No. 20060627 at 10). The rejection does not - and cannot - identify where in Misawa I and II there is disclosed "[a] process for

producing canthaxanthin and echinenone which comprises cultivating a recombinant microorganism, which is expressing a β -carotene ketolase gene, belonging to ***Xanthophyllomyces dendrorhous (Phaffia rhodozyma)*** ..." as recited in amended claim 1.

It is respectfully submitted that Misawa I and II do not disclose or suggest currently amended claim 1. Unfortunately for the Examiner, Hoshino fails to fill this factual gap. As conceded by the Examiner, Hoshino "do[es] not disclose the isolation of the beta-carotene ketolase gene from *Alcaligenes* PC-1 [] and expression of beta-carotene ketolase in said recombinant microorganism using control sequences or culturing the recombinant microorganism for 48-350 hours." (Paper No. 20060627 at 10). Hoshino discloses the cloning of astaxanthin synthase. In Hoshino, a specific mutant *Phaffia rhodozyma* ATCC 96815, which was blocked for the reaction from β -carotene to astaxanthin, was used as a transformation host. This mutant was transformed with genetic material from the chromosome of a wild-type strain of *Phaffia rhodozyma* ATCC 96594 for the purpose of identifying a genetic fragment complementing the reaction from β -carotene to astaxanthin in *Phaffia rhodozyma*. (Col. 8, lines 13-28). Thus, the mutation in the *Phaffia rhodozyma* strain ATCC 96815 was obtained by the gene from another strain of *Phaffia rhodozyma*. Hoshino fails to disclose or suggest to insert a polynucleotide sequence from ***another genus or strain of bacteria or algae*** into *Phaffia rhodozyma*, let alone the specific microorganisms, ***Agrobacterium aurantiacum***, ***Alcaligenes* PC-1**, ***Paracoccus marcusii*** MH1, a **gram-negative bacteria E-396 (FERM BP-4283)**, and ***Haematococcus pluvialis***, claimed in the instant process for producing canthaxanthin and echinenone. Thus,

Hoshino falls short of filling the factual gap left by Misawa I and II. For this reason also, the rejection should be withdrawn.

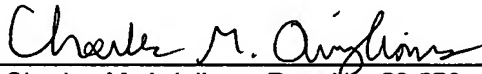
The rejection is also devoid of any discussion of the dependent claims. Accordingly, the record is devoid of any evidence that the Examiner individually considered the dependent claims. It is axiomatic, however, that a dependent claim is not *per se* unpatentable by a document that allegedly makes unpatentable the base claim. Accordingly, "[e]xaminers are reminded that a dependent claim is directed to a combination including everything recited in the base claim and what is recited in the dependent claim. ***It is this combination that must be compared with the prior art, exactly as if it were presented as one independent claim.***" MPEP § 608.01(n) (8th ed., Rev. 5, Aug. 2006, pp. 600-91). This the Examiner has not done. Accordingly, the rejection is also both factually and legally deficient as to the dependent claims. For this additional reason, the rejection should be withdrawn as to the dependent claims.

We further note that the § 103 rejection is inconsistent with the enablement rejection. In the enablement rejection, the Examiner asserts that the specification does not enable producing canthaxanthin and echinenone by using ***any*** β -carotene ketolase gene from ***any*** source. But, in seeking to combine Misawa I and Misawa II, the Examiner ignores his criticisms of the present specification. The Examiner cannot have his cake and eat it too. If the § 103 rejection is legally sound, then the enablement rejection is not. But, as noted above, even if the § 103 rejection does not run afoul of the enablement issues, it is still legally and factually deficient as noted above.

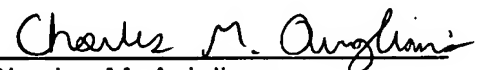
In view of the foregoing, it is respectfully submitted that the rejection has been rendered moot. Accordingly, withdrawal of the rejection is respectfully requested.

Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 7, 2007.


Charles M. Avigliano, Reg. No. 52,578

Respectfully submitted,

By: 
Charles M. Avigliano
Registration No. 52,578
BRYAN CAVE LLP
1290 Avenue of the Americas
33rd Floor
New York, NY 10104-3300
Phone: (212) 541-2000
Fax: (212) 541-4630